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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,387

01/05/2006

David Peter Shaw

PL10-002

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

01/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,387	Applicant(s) SHAW, DAVID PETER	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,14,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,14,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation in claims 1 and 10 describing the “intermeshing loops” has not been properly described in the Applicant's drawings and specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

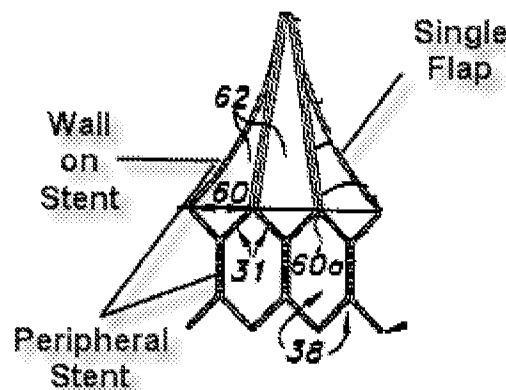
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-11, 14, 21, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by DiMatteo et al. (US Pat. No. 7,267,686). DiMatteo et al. discloses the following of claim 1: a prosthetic valve (10) in the form of a flap valve that includes at least one flap (40) arranged to allow movement of liquid through the valve only in one direction, the at least one flap being made entirely of a flexible openwork structure of a medically acceptable metal (col. 4, lines 33-

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44), wherein the flexible openwork structure is selected from the group consisting of: knitted wire and chainmail (Figs. 1-8).

Claim 2 is disclosed as shown in the following figure:



DiMatteo et al. discloses the following of claim 3: the prosthetic valve as claimed in claim 1 wherein said valve includes two flaps (40) arranged to close against each other.

DiMatteo et al. discloses the following of claim 4: the prosthetic valve as claimed in claim 3 wherein said valve further includes a peripheral stent (30) supporting a wall (31) extending at right angles to the plane of the stent and providing two opposed cutouts (62) in which said flaps are mounted.

DiMatteo et al. discloses the following of claim 5: the prosthetic valve as claimed in claim 1 wherein said valve includes three flaps (40) of similar size, arranged to close against each other.

DiMatteo et al. discloses the following of claim 6: the prosthetic valve as claimed in claim 5 wherein said valve also includes a peripheral rib (31) around the perimeter of the valve.

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DiMatteo et al. discloses the following of claim 7: the prosthetic valve as claimed in claim 5 wherein said valve further includes a peripheral stent (30) upon which the three flaps are mounted.

DiMatteo et al. discloses the following of claim 9: the prosthetic valve as claimed in claim 1 wherein the medically acceptable metal is titanium or a titanium alloy (col. 4, lines 33-44).

DiMatteo et al. discloses the following of claim 10: a method of promoting tissue growth and endothelialisation, minimizing the risk of foreign body infection following the fitting of a prosthetic valve in a living subject, said method including the provision of a prosthetic valve (10) in the form of a flap valve that includes at least one flap (40) arranged to allow movement of liquid through the prosthetic valve only in one direction and in which the one flap is made entirely of a flexible open work structure (Figs. 1-8) of a medically acceptable metal (col. 4, lines 33-44), wherein the flexible openwork structure is selected from the group consisting of: knitted wire and chainmail (Figs. 1-8).

DiMatteo et al. discloses the following of claim 11: the method as claimed in claim 10 wherein the prosthetic valve is a heart valve (col. 1, lines 16-18).

DiMatteo et al. discloses the following of claim 14: the method as claimed in claim 10 wherein the medically acceptable metal is titanium or a titanium alloy (col. 4, lines 33-44).

DiMatteo et al. discloses claims 21 and 22 as shown in Figures 1-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo et al. in view of Yang (US Pub. No. 2002/0138138). DiMatteo et al. discloses the invention substantially as claimed, however, DiMatteo et al. does not disclose placing an inert degradable coat over the valve. Yang teaches this coating in paragraph 0059 for the purpose of reducing the wear of the prosthetic parts. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this coating in order to reduce the wear of the prosthetic parts.

Response to Arguments

Applicant's arguments filed 9/8/2009 have been fully considered but they are not persuasive. The Applicant contends that the DiMatteo reference does not disclose any valve flaps made entirely of cover (80). The examiner respectfully disagrees. Figures 1-4 of DiMatteo show that cover (80) surrounds the entirety of flaps (40). In the instant case, the combination of the DiMatteo and the Zilla references will allow element (80) of DiMatteo to cover the mesh of Zilla. Since the claims use "comprising" language, it does not exclude additional materials being used to construct the device.

The Applicant further contends that the specification distinguishes the knitted wire from the woven wire, both with respect to appearance as well as stiffness. While the claim language should be read in light of the specification, language from the specification may not be read into the claims. Without an explicit definition of knitted wire and woven wire in the specification,

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these terms must be given their broadest, reasonable interpretation, which does not include references to “intermeshing loops.”

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774